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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/458,297 | 12/10/1999 | JOHN FIKES | 18623-014500 | 8696 |

28393 7590 08/06/2004

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVE., N.W.
WASHINGTON, DC 20005

EXAMINER

SCHWADRON, RONALD B

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1644

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,297

Applicant(s)

FIKES ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-145 is/are pending in the application.
- 4a) Of the above claim(s) 43-52, 54-74, 76-80, 83, 85 and 88-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41, 42, 53, 75, 81, 82, 84, 86 and 87 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Applicant's election of Group II and the peptide KTCPVQLWV in the paper filed 12/3/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 43-50,54-73,89-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in paper filed 12/3/2003.
3. Applicant's election without traverse of the species 9mer and peptide fused to a linker in the reply filed on 6/3/2004 is acknowledged.
4. Claims 51,52,74,76-80,83,85,88 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/3/2004.
5. Claims 41,42,53,75,81,82,84,86,87 are under consideration.
6. Applicant needs to update the status of all US applications disclosed in the specification.
7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it discloses priority claims to applications to which priority is no longer claimed in the instant application.
8. The amendment filed 2/6/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. The amendment filed 2/6/2004 to page 1, last sentence indicates that "All

of the above applications are incorporated herein by reference". A priority claim to PCT/US99/13789 has been added to page 1 of the specification wherein said application was not previously listed or "incorporated herein by reference". The "incorporated herein by reference" as it applies to PCT/US99/13789 constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

9. References not considered on the enclosed PTO-1449s were not considered because a copy of the reference was not included with the IDS. Foreign language publications supplied without a complete translation were only considered with regard to the English language abstract.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 41,42,53,75,81,82,84,86,87 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuebler et al. (WO 96/22067).

Kuebler et al. teach a p53 ratchet library that contains the 10mer peptide KTCPVQLWVD (see Example 6 and Figure 14, wherein the Figure refers to 10mer peptides derived from the sequence recited at the top of the Figure (AKA SEQ. ID. NO. 9 of Kuebler et al.) and wherein the second 10mer that begins with K is the aforementioned peptide). Figure 1A/1B shows how the ratchet libraries are derived wherein the library consists of all potential peptides of a designated size derived from a target sequence. The ratchet library contains all possible 10mer peptides found in the sequence recited in the top of Figure 14, wherein said sequence comprises the peptide KTCPVQLWV. The aforementioned peptide is "isolated" as per the definition of said word in page 12 of the specification.

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Kuebler et al. also teach 9mer peptide ratchet libraries derived from the p53 sequence recited in the top of Figure 14 (AKA SEQ. ID. NO. 9 of Kuebler et al., see claims 1,5,8,9). The 9mer ratchet library would contain the peptide KTCPVQLWV because said sequence is found in SEQ. ID. NO. 9 of Kuebler et al. and the ratchet library contains all the 9mers found in said peptide. The peptides can have attached linker amino acids (see page 14, last paragraph, continued on page 15, page 15, second complete paragraph). Kuebler et al. teach said peptides in a composition with a pharmaceutically acceptable carrier (see page 19, first incomplete paragraph). The aforementioned composition contains all peptides derived from a particular target antigen.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RONALD B. SCHWADRON

PRIMARY EXAMINER

GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.

Primary Examiner

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